Participant Information Sheet

Study: *RA-HEAL (**R**esilience **a**nd **Hea**lthy **L**ifestyle Program for People with Rheumatoid Arthritis)*

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What am I being invited to do?

This information describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

You have been provided with this information as you may be eligible for this research. This information may help you to decide whether you wish to be involved or not. Please feel free to discuss your participation, or any information in this document, with a team member or your health professional. You may take this consent form home to think about and discuss with family and friends.

Key Information

- Participation in this research is voluntary. If you don't wish to take part, you don't have to. Your medical care and any relationship with the affiliated universities won't be affected if you choose not to take part.
- You are being asked to take part in this study because you have been diagnosed with Rheumatoid Arthritis (RA).
- The purpose of this study is to better understand how to support people with RA to have positive wellbeing and healthy lifestyle behaviours and how this impacts their quality of life.
- Your participation in this study will last for two years.
- You will be participating in a randomised controlled research project. This means you will be randomly assigned to one of two study groups – neither you nor your doctor will have a choice in which group you are put in for the study.
- Assessment procedures will include joint exams, physical exams, and surveys.
- If you decide you want to take part in the research project, you will be asked to provide consent. By agreeing to provide consent you are telling us that you:
    - Understand what you have read.
    - Consent to take part in the research project.
    - Consent to have the tests and take part in the lifestyle interventions that are described.
    - Consent to the use of your personal and health information as described.

You will be given a copy of this *Participant Information and Consent Form (PICF)* to keep.

Participating in this study also involves participation in a combined biobank-registry study called the Australian Arthritis and Autoimmune Biobank Collaborative (A3BC). In addition to this consent, you will be asked to complete the A3BC Adult Biobank Participant Information Sheet and Consent Form (v5.3 or later).

Introduction

This research study is conducted by the Princess Alexandra Hospital, The University of Queensland, and Griffith University. Positive wellbeing and healthy habits are important for people with rheumatoid arthritis (RA). We want to know how we can help people with RA start and continue healthy and resilience activities. This research is comparing two different ways to help people with arthritis. Each option aims to give you more knowledge, confidence, and ability to access support networks, exercise regularly, eat healthily, quit smoking (if you smoke), and manage your thoughts and feelings about your RA.

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The study will last for two years, and about 150 people will take part. If you decide to participate in this research project, the study doctor will inform your local doctor and your rheumatologist.

What you need to know

Eligibility

To join this study, your rheumatologist will check that you:

- Are 18 years or older
- Were diagnosed with rheumatoid arthritis in the last 24 months
- Live in Brisbane, Ipswich or Logan area's (or a wider area if you are willing to travel to attend clinics and sessions)
- Can attend both in-person and online sessions
- Have your doctor's permission to join an exercise program
- Can give consent for the study and to join the A3BC Biobank-Registry
- Can participate for the full duration of the trial
- Aren't already in a formal self-management program for RA
- Aren't getting psychiatric, psychological, or counselling services

Randomisation and Group Assignment

You will be randomly put into one of two groups – **Program A** or **Program B**. You and your doctor won't choose the group. You have a 50% chance of being in either group. This study is not blinded. This means that once you have been assigned to your group, you will know which group you're in. This study is not testing any new drugs. If you are currently taking medication for your RA, keep taking it as your doctor advises, regardless of which group you are assigned to.

Exercise, healthy eating, not smoking and emotional wellbeing are essential for people with arthritis to maximise function, and to reduce disease activity and complications. This research is comparing two different programs designed to help people with arthritis. One is a structured program, and the other is self-directed. Both programs focus on lifestyle and wellbeing, and include continuous medical care from your chosen doctor, as well as regular extra assessment and follow-up.

Participation in Program A

If you're in Program A, you'll attend a structured program that includes a mix of in-person (on-site) and online (remote) training over 5 months (20 weeks). In-person sessions will be in one of four places: Princess Alexandra Hospital, University of Queensland St Lucia campus, Clem Jones Centre Wellness precinct at Carina, and Ipswich Hospital. Both remote/online and in-person groups will have a maximum of 10 people. The training is divided into 5 parts, each to

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help you improve your physical health, mental wellness, and eating habits. Refer to Figure 1 below for the schedule of intervention sessions.

1. ***Psychosocial Resilience Training*** – A clinical/health psychologist will lead small group sessions to help your resilience. There will be six 2-hour face-to-face sessions and two 1-hour teleconference sessions. Total time: 14 hours over 8 weeks.
2. ***Nutrition Counselling*** – You will have three individual sessions (one at the start of the program and 2 follow ups) with an accredited dietitian via teleconference to assess your current diet and to set personal goals. You will also take part in three group-based nutrition education sessions (1 hour each) by teleconference to help you make healthy meal plans. Total time: 5 hours over 12 weeks.
3. ***Exercise Training*** – You'll have an hour-long session with an exercise physiologist in Week 9 to understand what exercises suit you. Then, you'll do regular aerobic and strength training for 8 weeks, followed by online sessions for 4 weeks. Total time: 20 hours over 12 weeks.
4. ***Quit Smoking*** – You'll attend an online session and have 6 follow-up sessions with a tobacco treatment specialist to help you quit smoking. Total time: 7 hours over 7 weeks.
5. ***Change Support*** – A psychologist will lead sessions to help you understand and manage behavioural and lifestyle factors affecting your RA. There will be 4 one-hour online sessions, totalling 4 hours over 4 weeks.

If you are allocated to Program A, the Psychosocial Resilience Training will be conducted over the first 8 weeks of your participation in the study. After you complete the Baseline visit you will be randomised into the study.

The other components of Nutrition Counselling, Exercise Training, Smoking cessation (if applicable) and Change Support will then occur together over the next 12 weeks of your participation in the study.

At visit 3 (month 6), you will be asked to complete a program feedback survey to assist us in identifying which parts of the structured program worked well, and which did not. You will also be invited to participate in a focus group discussion (online) to provide any additional feedback not captured by the survey.

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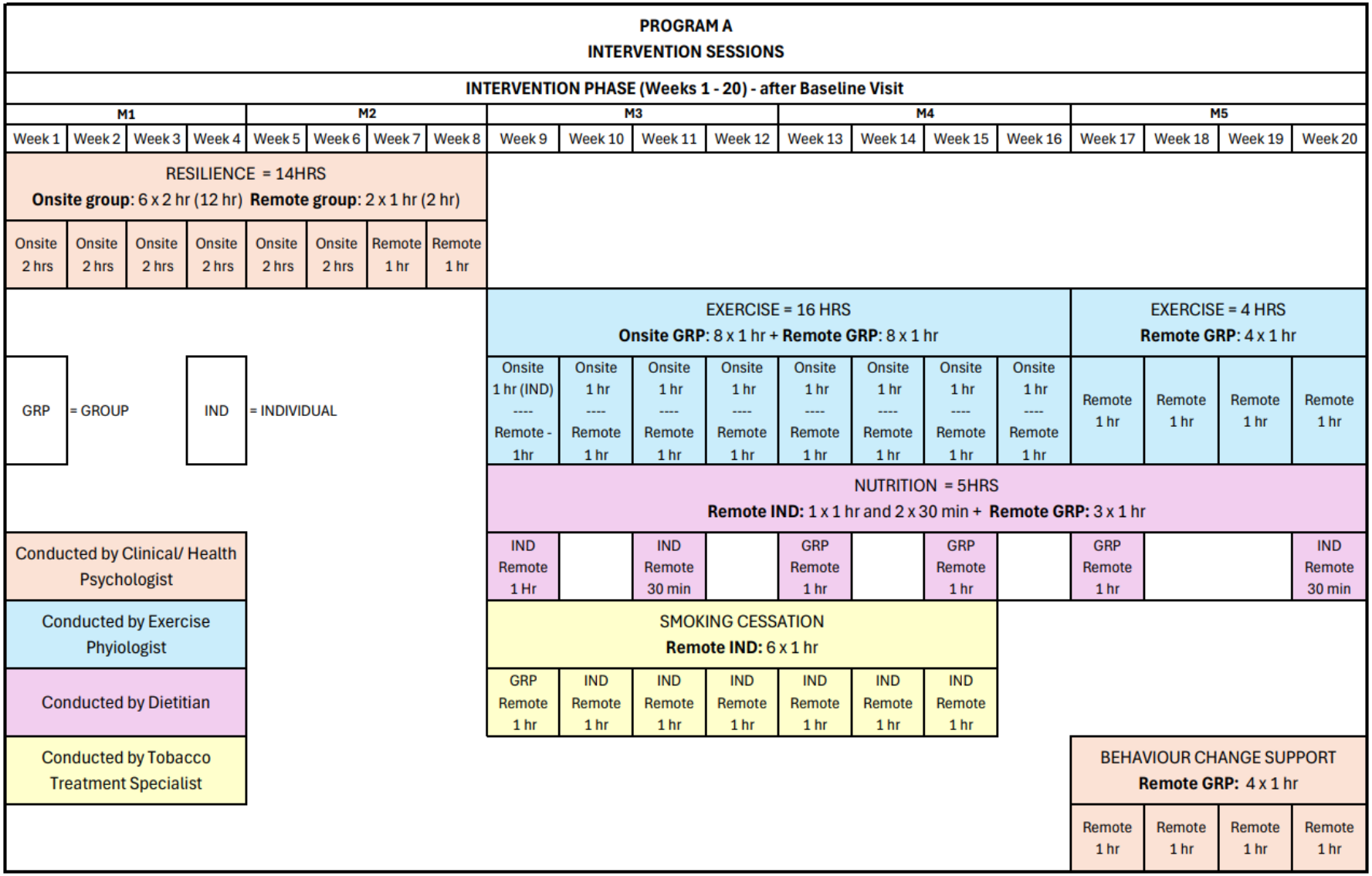
Figure 1. Program A Schedule of Intervention Sessions



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Participation in Program B

If you're in Program B, you'll be given written and verbal information to help you improve your physical health, mental wellness, and eating habits.

1. *Psychosocial Resilience* – maintaining a positive outlook and mental wellbeing. You'll receive tips on resilience and information on how to access The Arthritis Movement's (formerly Arthritis Queensland) support programs and peer to peer mentoring.
2. *Nutrition* – You will receive written information about healthy eating and arthritis.
3. *Exercise* – You'll receive tips on exercise training to support your RA care and information on how to access The Arthritis Movement's (formerly Arthritis Queensland) Arthritis Moves and Dance for Arthritis classes.
4. *Quit Smoking* – You'll receive written tips on how to Quit to support your RA self-management, and related services.
5. *Change Support* – You'll receive tips on how to manage behavioural factors affecting your RA and information on how to access The Arthritis Movement's support programs.

During this program you may choose to access any service or resource you believe is useful to you and use them as required. A diary will be provided for you to record any significant events that you experience between Month 1 and Month 6. You will also receive a brief monthly check-in through SMS, email, or phone from the research team to monitor potential safety events. Refer to Figure 2 below for the monthly check-in schedule.

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Figure 2. Program B Monthly Check-in Schedule (Months 1 to 6)

PROGRAM B STANDARD OF CARE - CONTROL GROUP																			
M1				M2				M3				M4				M5			
Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
Baseline Date				Monthly check-in				Monthly check-in				Monthly check-in				Monthly check-in			
Monthly Check-ins are conduted by either Phone call,Email or by SMS.																			

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Study Procedures Overview

Taking Part in Program A or Program B

Whilst participating in the study your RA will continue to be managed by your usual rheumatologist, and your usual medical care and health screening will continue to be provided by your usual general practitioner (GP), and any other specialists or allied health professionals they recommend.

Additional to your usual care you will see a rheumatologist member of our RA-HEAL study team every six months for two years after your initial baseline visit.

1. Screening Visit (Visit 1): You will be booked to attend the screening visit via telehealth/online to obtain your consent verbally, assess your eligibility for the study, and we will check your current medications and doses. You will be invited to consent to RA-HEAL (this study) and the A3BC. If you are interested, you can consent to receive a written summary of the project results upon completion of this study. We will collect some personal information from you including your contact details, your current rheumatologist, health insurance information, marital status, education level, smoking and alcohol consumption. When consenting to the A3BC, you may also authorise us to request additional health information from any other providers that you may see. This information will be entered into a secure database accessible only by the study team. Total 30 minutes

2. Baseline Visit (Month 1, Visit 2): We will obtain a written consent from you at this visit, by signing this form you are reading. We will also re-check your current medications and doses, and the study doctor or research nurse will conduct a joint count and physical examination to assess your health on the day. We will measure your strength and fitness using different physical function tests (grip strength using a dynamometer, a 6-minute walk test, 4-meter gait speed, 30 second arm curl, single leg balance and a timed up and go test). If you are a smoker, we will conduct a carbon monoxide breath test. You will complete a series of questionnaires about your health, quality of life, diet, smoking activity (if you smoke) and how arthritis affects your life. This can be completed online at your own convenience. The questionnaires will be sent to your email address about 2 weeks (14 days) prior to the commencement of the next intervention program. You will be issued with an Actigraph device to wear for 7 days. You will return this device in the pre-paid envelope supplied. An Actigraph is a small device worn on the wrist like a watch that records your activity, mobility and sleep.
3. Total 1.5 hours.

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4. Visit 3, 4, 5 & 6 (6-, 12-, 18- and 24-Month Visits): We will review any changes to your medications and RA symptoms. Like Visit 2, you will undergo a physical exam, complete a series of surveys, perform physical function tests, and be assessed for breath carbon monoxide (smokers only). Total 1 hour per visit.

Benefits and Risks

This study aims to understand how people with RA can start and maintain healthy activities to manage their symptoms. We hope that those who finish the program will feel more confident and knowledgeable about managing RA, including safe exercise and healthy eating. This could improve wellbeing, physical function, symptoms, and quality of life. However, you might not see direct benefits from the program.

If you get sick or injured during or because of the assessment or program, please tell our team right away. If you're not used to exercise, you might feel breathless, uncomfortable, or sore at first. Changing your diet or quitting smoking might also cause physical or mental changes. These usually get better with time. If they don't, talk to the project team or a health professional.

Keep taking your regular medications. Tell your study doctor and staff about any changes in your treatments or medications during the study, including over-the-counter meds, vitamins, herbs, acupuncture, or other treatments.

During the program, you might think about and discuss stress and emotions. If this worries you, our staff will help, and you can also get help outside the program. You can access a variety of services that offer 24-hour crisis support, suicide prevention and mental health services.
Lifeline Australia (13 11 14), Queensland mental health access line (1300 642 255), and Beyond Blue (1300 22 4636).

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How will my information be used for this project?

Online Data

We'll use the REDcap (Research Electronic Data Capture) tool for online surveys. The University of Queensland manages the RA-HEAL secure REDcap data. All data is stored on university servers and managed by university staff. After the research, survey data will be stored according to the University of Queensland's retention schedules. Some data might be stored on cloud services. The university has privacy measures in place.

All assessment information will be confidential, de-identified and stored using a unique identification number. We will ask for your name and date of birth which will then be replaced by a code. At the start of the research, we will request your contact details (email or telephone) to remind you of scheduled sessions and advise of any changes to the research. After study completion we will delete your personal information. Your name won't be in any study results, but your anonymous comments reflecting your experiences might be. Your data might be used in future related research, but it will be anonymous.

Who is running and paying for this project?

Sponsor Support

The sponsor of this study is The University of Queensland. It is funded through the Medical Research Future Fund (MRFF) - Effectiveness of a Healthy Lifestyle and Resilience Program in New-Onset Rheumatoid Arthritis 2024-2027.

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Who has reviewed and approved this project?

Research Project Ethics and Review

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023) and the National Health and Medical Research Council's guidelines. This program has been awarded clearance by Metro South Human Research Ethics Committee (HREC/2024/QMS/108779) University of Queensland (2025/HE000486) and Griffith University **(2025/238).**

Participation is completely voluntary. If you wish to withdraw from the study after it has started, you can do so at any time without having to give a reason. There are no consequences to you for withdrawing from the study and it will not affect the type of care you receive from any member of the program team, or your health care now or at any time into the future.

If you choose to withdraw you will be provided with a withdrawal form to sign. On the form you can select whether all your personal data already collected are destroyed or whether they can be kept by the researchers. The reason for keeping your data is to accurately detail the characteristics of all participants initially involved.

Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning study policies, information about conduct of the study or your rights as a participant, or should you wish to make an independent complaint, you can contact any of following:

- Metro South Human Ethics Committee Manager on 07 3443 8047
  or email MSH-Ethics@health.qld.gov.au

- The University of Queensland Ethics Coordinators on 07 3365 3924
  or 07 3443 1656 or email humanethics@research.uq.edu.au

- Griffith University Human Research Ethics Officer on 07 3735 4375
  or email research ethics@griffith.edu.au

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Trial Schedule of Visits

			On-study					*Exit evaluation*
Assessment		**Screening**	**Month 1 Baseline**	**20 Weeks**	**Month 6**	**Month 12**	**Month 18**	**Month 24**
		Visit 1	**Visit 2**	**Activities**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
1	Eligibility assessment	X						
2	Informed consent	X (Verbal)	X (Written)					
3	Initial screening survey	X						
4	Program A & B – Activities			X				
5	Medical assessment/ physical examination		X		X	X	X	X
6	Medical history/concurrent medications	X	X		X	X	X	X
7	Sociodemographic questionnaires		X		X	X	X	X
8	Wellbeing/lifestyle questionnaires		X		X	X	X	X
9	Blood Sampling		X		X	X		X
10	Actigraph		X		X			
11	Feedback survey				X	X	X	X
12	Focus group session				X			
13	Diary		X		X	X	X	

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Participant Consent Form – *Adult providing own consent*	PAH OUTPATIENT URN INSERT LABEL HERE GENDER ADDRESS PHONES
Title	Resilience and Healthy Lifestyle Program for People with Rheumatoid Arthritis
Short Title	RA-HEAL
Project Sponsor	The University of Queensland
Principal Investigator	Dr Katherine Poulsen
Location	The Princess Alexandra Hospital

Declaration by the participant

- I have read the Participant Information for this program, or have had it read to me.
- I understand the purposes, procedures, potential benefits, and risks of the research described.
- I have had an opportunity to ask questions, and I am satisfied with the answers I have received.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I understand that all assessment information will confidential, de-identified and stored securely using a unique identification (ID) number.
- I understand that the data from this study may be used in future related research, in which case my personal and contact details will not be made available, and my anonymity will be protected.

Consent for the FUTURE Use of My Information

- I agree to the storage and sharing of any information arising from this study which may be used for FUTURE related research.

YES ☐	**NO** ☐

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Consent for receipt of RESULTS of this study

- I would like to receive a written summary of the results of this study.

YES ☐	**NO** ☐

Name of Participant (please print) ----------

Signature ---------- Date ----------

Declaration by Researcher[‡]

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation. Verbal consent has been provided to the above statements

Name of Researcher (please print) ----------

Signature ---------- Date ----------

[‡]An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

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